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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,075	06/20/2003	Michael P. Boutillette	BSME120588	8875

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EXAMINER

STIGELL, THEODORE J

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 06/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/601,075	Applicant(s) BOUTILLETTE ET AL.	
	Examiner Theodore J. Stigell	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☒ Claim(s) 10 and 11 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/26/03, 10/18/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities: The term "ergometric" on page 4, line 8 should be replaced by the term "ergonomic".

Appropriate correction is required.

Claim Objections

Claims 10 and 11 are objected to because of the following informalities: It appears that the applicant may have inadvertently recited claims 10 and 11 as being dependent upon claim 7 instead of the independent claim 8. This application was examined with the assumption that claims 10 and 11 are actually dependent upon claim 8. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2,4, and 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Horzewski (5,364,376).

Horzewski clearly shows a guidewire exit tool that includes all of the limitations as recited in claims 1 and 2. See Figures 1 and 2 and the respective portions of the specification. Horzewski shows a guidewire exit tool with a handle (25) with a pin (24) attached thereto. In regards to claim 2, the pin (24) has a tapered end (26) that is

designed to engage a guidewire and lift it out of the guidewire channel of a rapid exchange catheter.

In regards to claim 4, Horzewski clearly shows a guidewire exit tool that includes all of the limitations as recited in claims 1 wherein the handle (25) has an oval configuration with a round configuration at the proximal end of the handle (25) which tapers to a more narrow configuration at the distal end of the handle (25). See Figure 1.

Horzewski clearly discloses a method of using a guidewire that includes all of the limitations as recited in claims 8-11. Horzewski discloses a method of using a guidewire in which a guidewire is loaded from the distal end of the catheter and passed to the proximal end of the catheter where the proximal end of the guidewire engages the tapered end (26) of the guidewire tool, which lifts the proximal end of the guidewire out of the guidewire lumen (16). See col.4, lines 10-18. In regards to claim 9, the pin (24) has a tapered end (26). In regards to claim 10 (examined as if dependent upon claim 8), the guidewire exit tool is placed in the distal end of the guidewire channel (16) and slides until it reaches the aperture (20) where it engages the guidewire. In regards to claim 11 (examined as if dependent upon claim 8), the proximal end of the guidewire engages with the tapered end (26) of the guidewire exit tool as the guidewire is loaded and slid from the distal end of the catheter to the proximal end of the catheter.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Ginn et al. (5,458,584).

Ginn et al. clearly discloses a guidewire exit tool that includes all of the limitations as recited in claim 1. See Figure 7 and the respective portions of the specification.

Ginn et al. clearly discloses a guidewire exit tool with a handle (104) with a pin (101) attached wherein the pin (101) engages with a guidewire (68).

In regards to claim 2, Ginn et al. clearly discloses a guidewire exit tool that includes all of the limitations as recited in claim 1 wherein the pin (101) has a tapered end that engages the guidewire (68). The pin (101) is wider at the very distal end and tapers to a narrower diameter at the beginning of the distal end to create a groove (103) that engages guidewire (68).

Claims 1-2, and 4-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Paoli (2,552,450).

Paoli clearly discloses a tool that includes all of the limitations as recited in claim 1. See Figures 1 and 2 and the respective portions of the specification. Paoli discloses a tool that has a handle (23) with a pin (21) attached thereto. The pin (21) is sized so that it is capable of fitting into the guidewire channel of a rapid-exchange catheter.

In regards to claim 2, Paoli discloses a tool that includes all of the limitations as recited in claim 1 wherein the pin (21) has a tapered end (35) that is capable of engaging a guidewire.

In regards to claim 4, Paoli discloses a tool that includes all of the limitations as recited in claim 1 wherein the handle (23) is oval-shaped with a pointed configuration at the proximal end of the handle (23) and a more rounded configuration at the distal end of the handle (23).

In regards to claim 5, Paoli discloses a tool that includes all of the limitations as recited in claim 4 wherein the handle (23) has an axis that is angled with respect to a

longitudinal axis of the pin (21). Any two intersecting axes are angled with respect to each other.

In regards to claim 6, Paoli discloses a tool that includes all of the limitations as recited in claim 4 wherein the handle (23) has a recessed, hollow center and a raised outer annular rim. See Figure 1.

In regards to claim 7, Paoli discloses a tool that includes all of the limitations as recited in claim 6, wherein the handle (23) has opposing recesses on both sides of the tool.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Horrocks (3,831,274).

Horrocks clearly discloses a tool that includes all of the limitations as recited in claim 1. See Figures 1 and 2 and the respective portions of the specification. Horrocks clearly shows a tool with a handle that consists of elements (1) and (7) with a pin (23) that is sized to fit in within a guidewire channel and engage a guidewire. The pin (23) has a broad, flat configuration that is capable of engaging a guidewire and lifting it up.

In regards to claim 2, Horrocks clearly discloses a tool that includes all of the limitations are recited in claim 1 wherein the pin (23) has a tapered end at element (27) that is capable of engaging a guidewire.

In regards to claim 3, Horrocks clearly discloses a tool that includes all of the limitations are recited in claim 1 wherein the pin (23) is secured to the handle by a web (15) that has a thickness that is smaller than that of the diameter of the pin (23).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent 6485466 B2 to Hamilton
US Patent 6497681 B1 to Brenner
US Patent 5460185 A to Johnson
US Patent 4054136 A to von Zeppelin
US Patent 3877429 A to Rasumoff
US Patent 6879854 B2 to Windheuser
US Patent 6723071 B2 to Gerdt
US Patent 5755685 A to Andersen
US Patent 6165167 A to Delaloye
US Patent Application 20030233043 A1 to Windheuser

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Stigell whose telephone number is 571-272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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TS



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